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2021 Position Statement From the International Society for the Advancement of Spine Surgery on Cervical and Lumbar Disc Replacement

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INTRODUCTION

Cervical and lumbar degenerative disc disease are well-known causes of neck and back pain and associated radiculopathy in spine patients. The estimated 1-year incidence rate of neck pain and any episode of lower back pain is 10.4% to 21.3%[1,2] and 1.5% to 36%,[3] respectively. Previous reports demonstrate significant socioeconomic effects of these common conditions.[4,5] Initial conservative treatment and ultimately fusion procedures or disc replacement are potential options for treatment of recalcitrant cervical and lumbar degenerative disc disease. Despite past reports of improved clinical outcomes with cervical and lumbar fusion procedures, there continue to be concerns of limiting motion at the affected segment and development of adjacent-segment degeneration and disease. Hilibrand et al[6] demonstrated that adjacent-segment disease occurred at a rate of 2.9% per year during the 10-year postoperative period following anterior cervical fusion. Other studies have reported even higher adjacent-segment degeneration and disease rates of 36%[7] and 50%[8] in the cervical spine. Past reports illustrate a wide range of the incidence rate (2.62% to 34%) of adjacent segment degeneration and disease after lumbar fusion.[9–11] These results led to the subsequent development of cervical and lumbar arthroplasty devices.

Currently, there are 8 Food and Drug Administration (FDA)-approved cervical and 3 FDA-approved lumbar total disc replacement (TDR) devices, not all of which are still commercially available. The aim of this review is to discuss the results of long-term follow-up studies, recent meta-analyses, and potential complications with cervical and lumbar TDR devices.

CERVICAL TOTAL DISC REPLACEMENT

Historical Background

The first use of cervical TDR (cTDR) dates back to the 1960s.[12] Currently, 8 devices have been approved by the FDA for single-level use in cervical arthroplasty: Prestige ST (Medtronic, Minneapolis, MN), ProDisc-C (Centinel Spine, LLC, West Chester, PA), BRYAN (Medtronic), SECURE-C (Globus Medical, Audubon, PA), PCM (NuVasive, Inc, San Diego, CA), Mobic-C (Zimmer Biomet, Warsaw, IN), Prestige LP (Medtronic), and M6 cervical disc (Orthofix, Lewisville, TX). Mobic-C and Prestige LP are also approved for 2-level use. The M6 device has most recently received premarket approval[13(p6)] and the Simplify disc has completed 1- and 2-level enrollment and is approaching FDA determination. The initial FDA investigational device exemption (IDE) trials for the currently approved cTDR devices demonstrated similar or greater improvement in outcomes of patients in the device group compared to anterior cervical discectomy and fusion (ACDF).[14–21] Similarly, meta-analyses of the these IDE trials illustrated similar improved outcomes with cTDR.[22,23]

Long-Term Follow-Up and Recent Meta-Analyses

Initial prospective, randomized controlled IDE trials have demonstrated equivalent or improved functional outcome results of cTDR compared to ACDF.[14–21] Mid- and long-term follow-up have

also demonstrated the overall positive success of arthroplasty compared to ACDF.[24–28] In an 8-year follow-up study of 21 patients, Quan et al[24] reported that the majority of patients with the BRYAN disc continued to have favorable results. Burkus et al[25] reported at 36 and 60 months the arthroplasty group had statistically significant better neck disability index scores ($P = .008$ and .022, respectively) as wel as neurologic recovery ($P = .004$ and .051, respectively) when compared with an ACDF. Coric et al[26] reported significant, sustained improvement in range of motion in patients with cTDR (BRYAN disc or Kineflex-C) compared to ACDF at 4-year follow-up. In a 5-year follow-up study, Zigler et al[27] demonstrated that both groups (Prodisc-C and ACDF) had statistically significant improved clinical outcomes compared to baseline but patients with Prodisc-C had greater improvement in reported neck pain. At 4-year follow-up, Delamarter et al[28] reported improved visual analogue scale (VAS) neck score in patients with Prodisc-C compared to ACDF.

Recently, longer-term follow-up (5 years or greater) studies continue to demonstrate successful results of arthroplasty compared to ACDFs, with lower rates of reoperation.[29–35] Janssen et al[29] reported that both groups (Prodisc- C and ACDF) continued to have improved patient satisfaction with surgery and neurologic status at 7-year follow-up. Both groups reported similar positive outcomes; however, fewer patients in the Prodisc group (7%) had secondary surgery compared to those with ACDF (18%).[29] In a 10-year follow-up of the IDE study, Gornet et al[30] reported stable results for the Prestige LP group with patient-reported outcomes, neurological status, and overall success. The authors also reported that the average motion at the index and adjacent level was maintained at 10-year follow-up and concluded that the device continued to have safe and effective results.[30] Lavelle et al[31] reported 10-year outcomes for patients with the BRYAN cervical disc. The authors reported statistically significant improvement in overall success (81.3% versus 66.3%) and neck and disability index (NDI) score in patients with cTDR compared to the ACDF group.[31] Although the results were not shown to be statistically significant, patients with the BRYAN disc had a lower rate of secondary surgeries compared to those with ACDFs (9.7% versus 15.8%; $P = .146$).[31] Phillips et al[32] reported 7-year follow-up of the FDA IDE trial for the PCM device demonstrated greater improvement with NDI, VAS neck pain, physical component score and mental component score of the Short Form-12 than with the control ACDF. The authors also reported decreased trends in secondary surgeries (3.6% versus 7.6%).[32] Hisey et al[33] reported, at 5-year follow-up, similar improvements in NDI, VAS neck and arm pain, and Short Form-12 scores for both groups (Mobic-C and ACDF). Additionally at 7-year follow-up for Mobic-C, Radcliff et al[36] reported improvement in patient-reported outcomes (NDI, VAS neck/ arm pain, Short Form-12 mental and physical component scores) for both the cTDR and ACDF group. The authors reported a statistically significant greater patient satisfaction in the cTDR group compared to ACDF.[36] Burkus et al[34] reported maintained or improved neurologic status in patients with cTDR (Prestige disc) compared to ACDF from a 5- to 7-year period. Vaccaro et al[35] reported statistical superiority in overall success (79.2% and 63.6%) and patient satisfaction (96% versus 88.8%) in the SECURE-C investigational group compared to ACDF at 7-year follow-up.

Previously in a meta-analysis, McAfee et al[22] demonstrated that patients who had undergone arthroplasty achieved greater overall clinical success compared to ACDF patients (77.6% versus 70.8%). In a meta-analysis of 3 FDA IDE randomized controlled trials (RCTs), Udaphyaya et al[23] reported greater neurologic success and lower rate of secondary surgeries for the cTDR group compared to the ACDF group. More recently, Gao et al[37] reported improved neurologic success and neck or arm pain (VAS) scores, fewer secondary surgeries, and increased motion at the index level in patients with cTDR versus ACDF. Similarly, a meta-analysis conducted by Zhang et al[38] reported improved neurologic success in the arthroplasty group compared to ACDF. The authors also reported superiority in NDI, neck and arm pain (Numeric Rating Scale) scores, and fewer secondary surgical procedures at the index level.[38]

Adjacent-Segment Disease

Long-term follow-up has facilitated further understanding of radiographic adjacent-segment degeneration and symptomatic adjacent-segment disease with cervical arthroplasty. Phillips et al[32] reported more frequent radiographic adjacent-segment degeneration with ACDF compared to cTDR at 7-year follow-up. Hisey et al[33] demonstrated that

adjacent-segment degeneration at the superior level was significantly lower for cTDR patients than ACDF at 5-year follow-up. Similarly, Burkus et al[34] reported lower rates of additional adjacent-level surgeries in the cTDR group compared to ACDF at 7-year follow-up. Vaccaro et al[35] also demonstrated that fewer SECURE-C patients (17%) reported symptoms related to the adjacent level(s) compared to ACDF patients (37.5%) at 7-year follow-up. Janssen et al[29] reported fewer surgical procedures involving the adjacent level(s) in the ProDisc-C group compared to the ACDF group at 7-year follow-up. At 10-year follow-up, results from Lavelle et al[31] and Gornet et al[30] also demonstrated lower rates of revision surgeries for the adjacent level in the cTDR group compared to the ACDF groups (BRYAN and Prestige LP, respectively).

In a review of 52,395 cases, Kelly et al[39] reported that short-term readmission was lower in the cTDR group ($P = .048$) as well as secondary surgery in the cTDR compared to the ACDF group within 90 days of surgery (2.04% versus 3.35%, $P = .015$); however, there was no difference in rates at long-term follow-up (1, 3, 5 years postoperatively) between the 2 cohorts. While the authors concluded that there was no protective benefits for single-level degenerative disease with cTDR compared to ACDF, this is may be secondary to the significant limiation of this being a large database study that will only identify long-term issues in patients who undergo a revision at a nonfederal hospital in California. Patients who have revisions at any other hospital system will not be identified.[39]

Various meta-analyses have been conducted in attempts to further clarify potential benefits of arthroplasty compared to ACDF.[40–42] Verma et al[40] reported that although there were more patients in the ACDF group requiring adjacent-level surgery at 2- to 5-year follow-up than in the cTDR group (6.9% versus 5.1%), the differences in rate of reoperation between the 2 groups was not statistically significant. In a meta-analysis of 32 studies, Shriver et al[41] reported an increased incidence of adjacent degeneration and disease in cervical arthroplasty with long-term (more than 2 years) follow-up. Zhu et al[42] combined the results of 14 RCTs with long-term follow-up (2 to 7 years) and reported that cTDR had lower rates of adjacent segment disease and fewer reoperations at the adjacent level. Although the meta-analysis by Luo et al[43] included fewer RCTs, the authors similarly concluded that cTDR had lower rates of adjacent segment disease compared to ACDF at 2-year follow-up.

Approval for 2-Level Use

In 2013, Mobic-C was approved for 2-level use. In the IDE trial conducted at 24 centers, results demonstrated significant greater overall success of 2-level total disc arthroplasty with Mobic-C over ACDF.[20] Since then, studies have demonstrated positive mid-term and long-term follow-up for 2-level cervical disc arthroplasty using the Mobic-C device.[44,45] In a 4-year post-hoc comparison, Bae et al[46] reported that there were no statistical differences in clinical outcomes or overall success of the cTDR group compared to ACDF. In a 7-year follow-up study of the original IDE clinical trial, Radcliff et al[36] demonstrated that the 2-level cTDR group had a significant improvement in NDI score, increased patient satisfaction rate, and decreased rate of reoperation at the index and adjacent level compared to ACDF.

Prestige LP is also currently approved for 2-level cervical disc arthroplasty. In the IDE RCT, Gornet et al[47] demonstrated that the investigational group undergoing 2-level cervical disc arthroplasty had greater overall success than 2-level ACDF. Lanman et al[48] also demonstrated that the 2-level Prestige LP group had statistically greater improvement in NDI score, neurologic status, and overall success at 7-year follow-up. The investigational group also had preserved motion and fewer secondary surgeries than the ACDF group at long-term follow-up.[48]

Devices With Recent Approval/ Currently in the FDA IDE Process

The M6-C device recently received premarket approval in 2019. In a feasibility study, M6 demonstrated comparable results to other cTDR devices.[49] This device has an artificial annular (polyethylene weave) and nuclear (viscoelastic polyurethane core) component to better mimic the natural human intervertebral disc and range of motion.[50] Reyes-Sanchez et al[51] demonstrated improved NDI score, neck and arm pain, and physical component score of Short Form-36 with no serious adverse events at 24 months. The authors also reported that the mean range of motion returned to approximated pretreatment levels (12.2° versus 11.1°) by 24 months.[51] Similarly, Thomas et al[52] also reported improved results for

NDI, VAS, and Short Form-36 scores in patients with the M6 device. Phillips et al[53] reported 2-year results of the IDE study with significant improvement for M6-C subjects, compared to ACDF controls, in overall Short Form-36 PCS scores and Neck and Arm Pain scores. Significantly fewer M6-C subjects utilized pain medication or opioids at 24 months as compared to ACDF controls. Range of motion was maintained in M6-C subjects. Neck Disability Index improvement, subsequent surgical interventions, dysphagia rates, and serious adverse events were comparable between groups.

The Simplify Disc™ has recently received FDA approval for single-level use. Early results from Geisler et al[54] demonstrated improved NDI and VAS neck and arm pain for patients with the Simplify Disc. Two-level use studies with the Simplify Disc have completed patient enrollment and are in the investigational pipeline for approval.

Potential Complications

Possible complications with cervical disc arthroplasty include heterotopic ossification, subsidence or migration, device wear and tear, and adjacent-segment disease.[55] Recent evidence continues to report low rates of reoperation at both the index and adjacent levels.[29,30,33,45,56–58] Past reports report a broad range (7.3% to 69.2%) for heterotopic ossification rate.[59–61] In a meta-analysis evaluating adverse events of total disc replacements, Anderson et al[62] reported that there were no statistical differences in dysphagia, heterotopic ossification, or overall incidence of neurologic deterioration between the cervical disc arthroplasty group and ACDF group. The authors also reported that the cTDR group had a lower relative risk of surgically related neurologic events and secondary surgeries compared to ACDFs.[62]

LUMBAR TOTAL DISC REPLACEMENT

Historical Background

The first use of lumbar total disc replacement dates back to the 1960s.[12,63] The first model of the Charité device was developed in the 1980s and subsequent models received FDA approval in 2004.[64] Initial studies of this device reported improved clinical and radiographic success compared to fusion.[65–67] Currently, the activL Artificial disc (Aesculap Implant Systems) and the Prodisc-L (Centinel Spine) are the only 2 commercially available FDA-approved devices. Other lumbar devices had completed premarket approval studies (Maverick, Flexicore, Kineflex, but either withdrew before FDA consideration or declined to sell commercially in the United States.

Results of Current Approved Devices

The Prodisc-L was approved by the FDA in 2006. This device consists of 3 components: upper and lower plates composed of cobalt-chrome molybdenium alloy (CoCrMo) and a monoconvex ultrahigh-molecular-weight polyethylene inlay.[68] Combined, these components form a spherical articulating device resembling a ball and socket joint.[68] In a randomized controlled FDA IDE trial, Zigler et al[69] demonstrated that patients with Prodisc-L had improved patient reported outcomes (Oswestry Disability Index [ODI], Short Form-36, and VAS pain), and neurologic success compared to patients with circumferential spinal fusion at 2-year follow-up. In a 5-year follow-up of the FDA IDE trial, Zigler and Delamarter[70] reported that both groups maintained improved patient-reported outcomes. The authors also reported fewer secondary surgeries at the index level and acceptable range of motion in the lumbar TDR group compared to the control group.[69] With an alternate analysis including additional FDA parameters, 48.1% of TDRs and 41.1% of fusions were overall statistical successes using a complex success formula.[70] In an RCT FDA IDE trial for 2-level use, Delamarter et al[71] reported that more patients in the lumbar TDR group (58.8%) reached statistical overall success than the fusion group (47.8%) at 2-year follow-up, using a similar complex success definition.

The ActivL artificial disc was approved in June 2015. This device consists of 2 metal endplates and 1 semiconstrained ultrahigh-molecular-weight polyethylene inlay.[72] The polyethylene core supports anterior and posterior translational direction, potentially reducing biomechanical stress at the facet joints and adjacent levels.[72] In the randomized controlled FDA IDE trial, Garcia et al[74] reported that the device was noninferior to the control devices (Charité or Prodisc-L). The authors also reported improved results for return to work, radiographic success (59% versus 43%), and ODI success (75% versus 66%) in the activL group compared to the control group at 2-year follow-up.[73] The activL group also had decreased serious adverse events related to the device (12% versus

19%) and similar surgical reintervention rates (2.3% versus 1.9%) compared to controls; however, these results did not reach statistical significance.[73] In addition, the activL group had improved range of motion with segmental rotation (0.9° versus -1.4° ; $P < .01$) and translation (+0.6 mm versus +0.2 mm; $P < .001$) but not with lateral rotation (+0.6 mm versus + 0.8 mm, $P = .52$).[73] Additionally, a greater percentage of patients with activL had an increase in disc height (>3 mm) than the control group (94% versus 87%, $P = .09$).[73]

Currently, there are limited reports on long-term follow-up for activL. In a randomized, controlled FDA IDE study with 5-year follow-up, Yue and Garcia[74] reported improvement in back pain severity and patient satisfaction in the activL group compared to the control group, but these results did not achieve statistical significance. The authors also reported no significant differences observed with range of motion (flexion/extension, translation, and lateral rotation) or disc height between the 2 groups.[74] Comparable results relating to serious adverse events were reported in both groups (58% versus 40%, $P < .01$).[74]

A recent meta-analysis conducted by Zigler et al[75] of 4 RCTs with long-term follow-up demonstrated improved ODI scores, decreased risk of reoperation, and increased likelihood of patient satisfaction with TDR compared to fusion. This meta-analysis included 3 FDA IDE studies as well as 1 non-IDE prospective randomized trial outside the United States, all with 5-year follow-up. Rao et al[76] conducted a meta-analysis of 7 RCTs with 2-year follow-up. Similarly, the authors reported improvements in ODI score, in addition to improved VAS score and shorter length of hospitalization. Ding et al[77] reported conflicting results regarding the superiority of lumbar TDR after reviewing 5 overlapping meta-analyses. But, the authors also reported the potential of lumbar TDR as an alternative treatment to fusion based off of short-term results.

Various devices that are approved outside of the United States have published reports with long-term follow-up. Although not a randomized controlled study, Aghayev et al[78] reported improved VAS leg and back scores and quality of life improvement (EQ-5D) in patients with lumbar TDR at 5-year follow-up. Implants included in this study were ActivL, Charité, Maverick, and Prodisc-L. The authors also reported the overall rates of complications and adjacent segment degeneration as 23.4% and 10.7%, respectively.[78]

Adjacent-Segment Disease

Past reports have attempted to further clarify the potential incidence rate and prevalence of adjacent-segment degeneration and disease after arthroplasty compared to fusion. Harrop et al[9] reported a significant decrease in incidence rate of adjacent-segment degeneration (9% versus 34%) and disease (1% versus 14%) with lumbar TDR compared to fusion. In analyzing data from a prospective multicenter study, Zigler et al[79] reported fewer changes in adjacent-level degeneration in the lumbar TDR group compared to fusion (9.2% versus 28.6%) at 5-year follow-up. The authors also reported a decrease in new findings of adjacent-level degeneration (6.7% versus 23.8%) and secondary surgery (1.9% versus 4.0%) in the lumbar TDR group compared to fusion.[79] In a meta-analysis of 13 studies, Ren et al[80] also demonstrated decreased prevalence and reoperation rate in the lumbar TDR group compared to fusion for short-term and long-term follow-up.

Approval for 2-Level Use

Multi-level lumbar disc replacement has been described in the literature since 2005, when Bertagnoli et al[81] described hybrid constructs including lumbar ADR at 2 and even 3 levels. Erkan et al[82] published data about the biomechanics of 2-level lumbar disc replacement in 2009. In 2011, Delamarter et al[83] published the 2-year outcomes analysis of the IDE study of ProDisc-L TDR compared to circumferential arthrodesis, demonstrating maintained range of motion at both implanted levels, equivalent or better VAS and ODI scores compared to fusion patients, and statistically significantly fewer reoperations (2.4% versus 8.2%, $P = .0497$) and significantly lower narcotic usage rates (36.4% versus 61.0%, $P = .0017$) in TDR versus fusion patients.

Published positive outcomes in smaller cohorts of 2-level lumbar TDR in military personnel with 28-month follow-up[84] and in single-site 2-level IDE patients at 9- to 10-year follow-up[85] were followed by an examination of secondary surgery rates at 5-year follow-up in the 229 patients from the initial ProDisc-L 2-level IDE study by Radcliff et al,[86] showing that "fewer patients underwent secondary

surgery at adjacent levels in the TDR patients compared with the fusion controls."

In April 2020, the FDA approved expanded use of ProDisc-L "to include treatment of up two consecutive lumbar spinal sections (levels) from L3-S1."[87] The indications were expanded to patients who "Have a condition in which pain is caused by wear-and-tear on a spinal disc (DDD) at one or two consecutive levels in the lumbar spine."[87]

Potential Complications

Implant-related complications can include collapse, subsidence, or dislocation.[78,88,89] Additional concerns with lumbar arthroplasty include approach-related complications, osteolysis secondary to polyethylene wear, heterotopic ossification and reoperation at the index or adjacent level.[90] Past reports demonstrate low or similar rates of reoperation with lumbar TDR compared to fusion.[69,70,73,75,76,91] In a meta-analysis conducted by Hiratzka et al,[92] patients in the lumbar fusion group had a 2-fold increased risk of adverse events compared with lumbar TDR with 2-year follow-up but the relative risk remained stable at 5-year follow-up. Additionally, these pooled data were from a limited number of RCTs due to a lack of consistency with reporting and describing adverse events in the various trials.[92]

CONCLUSION

Currently, there is compelling level I and II evidence with long-term follow-up that supports the use of cervical and lumbar TDR as a viable alternative to fusion procedures for appropriately selected patients. Those with exclusions per FDA labelling should not be considered for arthroplasty.

Although some of these data are derived from industry sponsored trials, there are multiple layers of independent and governmental oversight, as well as peer review prior to publication. Recent evidence and comparison with meta-analyses continue to demonstrate positive outcomes and benefits over time, even with with expanded 2-level use in the cervical spine. Studies now following patients out to 5 to 10 years continue to show positive results for these devices.

Based on the above review of the available evidence-based scientific literature (much of it level I), the International Society for the Advancement of Spine Surgery, as a global organization of spine surgery professionals, strongly supports both cervical and lumbar total disc replacements, including multi-level use as approved by the FDA, as safe and effective treatment alternatives to fusion in appropriately selected patients. FDA study guidelines and labelling regarding inclusion and exclusion criteria should be followed for use, as supported by a strong published database.

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